General

Guideline Title

Traditional Chinese medicine treatment guideline for primary headache disorders.

Bibliographic Source(s)

> Guangdong Provincial Hospital of Chinese Medicine. Traditional Chinese medicine treatment guideline for primary headache disorders. Guangdong Sheng (China): Guangdong Provincial Hospital of Chinese Medicine; 2018 Jan 30. 5 p. [44 references]

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

NEATS Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report Clinical Practice Guidelines We Can Trust.

▊▯▯▯▯= Poor ▊▊▯▯▯= Fair ▊▊▊▯▯= Good ▊▊▊▊▯= Very Good ▊▊▊▊▊= Excellent

Assessment	Standard of Trustworthiness
YES	Disclosure of Guideline Funding Source
▊▊▯▯▯	Disclosure and Management of Financial Conflict of Interests
	Guideline Development Group Composition
YES	Multidisciplinary Group
YES	Methodologist Involvement

▥	Patient and Public Perspectives
	Use of a Systematic Review of Evidence
▥	Search Strategy
▥	Study Selection
▥	Synthesis of Evidence
	Evidence Foundations for and Rating Strength of Recommendations
▥	Grading the Quality or Strength of Evidence
▥	Benefits and Harms of Recommendations
▥	Evidence Summary Supporting Recommendations
▥	Rating the Strength of Recommendations
▥	**Specific and Unambiguous Articulation of Recommendations**
▥	**External Review**
▥	**Updating**

Recommendations

Major Recommendations

Definitions of the strength of recommendations (Strong, Weak, No clear recommendation) are provided at the end of the "Major Recommendations" field.

<u>Recommendations</u>

Migraine

Acupuncture (Strength of recommendation: Strong; Quality of evidence: Low)

Tianshu capsule (Strength of recommendation: Weak; Quality of evidence: Low). Its active ingredients are ligusticum wallichii and rhizoma gastrodiae.

Chuanxiong chatiao powder (Strength of recommendation: Weak; Quality of evidence: Very low). Its active ingredients are ligusticum wallichii, angelica dahurica, notopterygium root, asarum sieboldii, radix sileris, schizonepeta, mint and liquorice.

Duliang capsule (Strength of recommendation: Weak; Quality of evidence: Very low). Its active ingredients are ligusticum wallichii and angelica dahurica.

Toutongning capsule (Strength of recommendation: Weak; Quality of evidence: Low). Its active ingredients are glabrous greenbrier rhizome, rhizoma gastrodiae, radix polygonum multiflorum preparata, angelica sinensis, radix sileris and medicinal scorpion.

Blood-letting (Strength of recommendation: Weak; Quality of evidence: Low)

Yangxueqingnao granule (Strength of recommendation: Weak; Quality of evidence: Low). Its active ingredients are angelica sinensis, ligusticum wallichii, white paeonia, prepared rehmannia root, uncaria, caulis spatholobi, selfheal, semen cassiae, nacre, rhizoma corydalis and asarum.

Tension-type Headache

Acupuncture (Strength of recommendation: Strong; Quality of evidence: Moderate)

Tuina (Massage) (Strength of recommendation: Strong; Quality of evidence: Moderate)

Yangxueqingnao granule (Strength of recommendation: Weak; Quality of evidence: Very low). Its active ingredients are angelica sinensis, ligusticum wallichii, white paeonia, prepared rehmannia root, uncaria, caulis spatholobi, selfheal, semen cassiae, nacre, rhizoma corydalis and asarum.

Toutongning capsule (Strength of recommendation: Weak; Quality of evidence: Very low). Its active ingredients are glabrous greenbrier rhizome, rhizoma gastrodiae, radix polygonum multiflorum preparata, angelica sinensis, radix sileris and medicinal scorpion.

Acupoint injection (Strength of recommendation: None; Quality of evidence: Very low)

Cluster Headache

Acupuncture (Strength of recommendation: Weak; Quality of evidence: Low)

Toutongning capsule (Strength of recommendation: Weak; Quality of evidence: Very low). Its active ingredients are glabrous greenbrier rhizome, rhizoma gastrodiae, radix polygonum multiflorum preparata, angelica sinensis, radix sileris and medicinal scorpion.

Tianma injection (Strength of recommendation: None; Quality of evidence: Very low). Its active ingredient is rhizoma gastrodiae.

<u>Definitions</u>

Strength of Recommendation

Recommendation	Benefits and Risks
Strong "Must do"	Benefits clearly outweigh risks
Weak "Might do"	Benefits might outweigh risks
No clear recommendation	Benefits are equal to risks OR uncertain
Weak "Might do"	Risk might outweigh benefits
Weak "Must not do"	Risks clearly outweigh benefits

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Primary headache disorders (migraine, tension headache, cluster headache)

Note: Diagnosis of primary headache refers to the International Classification of Headache Disorders, 2nd Edition (ICHD-II).

Guideline Category

Treatment

Clinical Specialty

Family Practice

Neurology

Intended Users

Physicians

Guideline Objective(s)

- To provide Traditional Chinese Medicine therapy guidelines for migraine, tension-type headache and cluster headache based on systematic reviews
- To address the following key questions:
  - Key Question 1: Is acupuncture effective for patient with migraine?
  - Key Question 2: Is tianshu capsule effective for patient with migraine?
  - Key Question 3: Is chuanxiong chatiao powder effective for patient with migraine?
  - Key Question 4: Is duliang capsule effective for patient with migraine?
  - Key Question 5: Is toutongning capsule effective for patient with migraine?
  - Key Question 6: Is blood-letting effective for patient with migraine?
  - Key Question 7: Is yangxueqingnao granule effective for patient with migraine?
  - Key Question 8: Is acupuncture effective for patient with tension-type headache?
  - Key Question 9: Is tuina effective for patient with tension-type headache?
  - Key Question 10: Is yangxueqingnao granule effective for patient with tension-type headache?
  - Key Question 11: Is toutongning capsule effective for patient with tension-type headache?
  - Key Question 12: Is acupoint injection effective for patient with tension-type headache?
  - Key Question 13: Is acupuncture effective for patient with cluster headache?
  - Key Question 14: Is toutongning capsule effective for patient with cluster headache?
  - Key Question 15: Is tianma injection effective for patient with cluster headache?

Target Population

Adults (aged ≥18 years) with headache

Note: Juveniles and pregnant women are not included.

Interventions and Practices Considered

1. Acupuncture
2. Chinese patent drugs
   - Tianshu capsule
   - Chuanxiong chatiao powder
   - Duliang capsule
   - Toutongning capsule
   - Tianma injection
   - Yangxueqingnao granule
3. Acupoint injection

4. Blood-letting
5. Tuina

Major Outcomes Considered

- Clinical efficacy rate
- Visual analogue scale (VAS)
- Headache frequency
- Headache duration
- Incidence of adverse reaction

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

<u>Search Strategy of Systematic Reviews</u>

Chinese Databases

The guideline development team searched Chinese databases (China National Knowledge Infrastructure, WANFANG DATA, China Biology Medicine and VIP). They ran the search with the date restrictions of database inception through October 2015.

English Databases

The guideline development team searched English databases (PubMed, EMBASE, Cochrane Library and Web of Science). They ran the search with the date restrictions of database inception through December 2015.

<u>Search Strategy of Original Research</u>

After the search of existing systematic reviews, there were still some clinical questions the guideline development group needed to answer. So, they searched the original research to develop new systematic reviews. They searched Chinese databases (China National Knowledge Infrastructure, WANFANG DATA, China Biology Medicine) and English databases (PubMed, EMBASE, Cochrane Library and Web of Science). They ran the search with the date restrictions of database inception through March 2016. Refer to the Appendix (see the "Availability of Companion Documents" field) for searches of different clinical questions.

<u>Study Selection</u>

Two independent reviewers conducted title scans and advanced articles if either one thought them relevant. The abstract review phase was designed to identify studies reporting the effectiveness or safety of the intervention. Two investigators independently reviewed abstracts. Differences between investigators regarding the inclusion or exclusion of abstracts were resolved through consensus adjudication. Full articles underwent another independent parallel review regarding their appropriateness for inclusion. Refer to the Appendix (see the "Availability of Companion Documents" field) for selection criteria for systematic reviews and original studies.

Number of Source Documents

A total of 3965 records were identified through database searching. After removing duplicates, the guideline development group included 2685 systematic reviews. After reviewing titles, abstracts, they included 96 systematic reviews. Finally, after reviewing the full text, a total of 43 systematic reviews were included.

See Appendix 10 (see the "Availability of Companion Documents" field) for literature search results of original studies presented by key question.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Strength of the Body of Evidence	Definition
High	Very confident that the true effect lies close to that of the estimate of the effect.
Moderate	Moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low	Confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect.
Very low	Very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of the effect.

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Data Extraction

Data extraction was conducted in the development of new systematic reviews. The guideline development group used standardized forms from the previous reviews as templates for data extraction and pilot tested them for the new medications and outcomes. By creating standardized forms for data extraction, they sought to maximize consistency in identifying all pertinent data available for synthesis.

For all articles, the reviewers extracted information on the general study characteristics (e.g., title, study site, source of funding, study design, study period); study participants (e.g., age, gender, inclusion criteria); interventions (e.g., characteristic, frequency of use, duration of use), comparisons and the outcome results.

For continuous outcomes, they extracted the mean difference between groups and a measure of dispersion. For dichotomous outcomes, they extracted the number of events and the number of participants in each group.

Quality Evaluation

Quality Evaluation of Existing Systematic Reviews

Two independent reviewers assessed the quality of existing systematic reviews. They assessed the quality of existing systematic reviews using the Revised Assessment of Multiple Systematic Reviews (R-AMSTAR). It could produce quantifiable assessments of systematic review quality.

Risk of Bias Assessment of Individual Studies

They evaluated the risk of bias in individual randomized controlled trials (RCTs) using the Cochrane risk of bias (RoB) tool.

Data Synthesis

Data synthesis was conducted in the development of new systematic reviews. The guideline development group conducted meta-analyses when there were sufficient data (at least 2 trials) and studies were sufficiently homogeneous. They tested the heterogeneity among the trials considered for quantitative pooling using a chi-squared test with a significance level of alpha less than or equal to 0.05, and also examined heterogeneity among studies with an I^2 statistic. They pooled the mean difference/risk ratio between groups using a random-effects model with the low heterogeneity ($I^2 < 50\%$) or fixed-effects model with no heterogeneity.

Strength of the Body of Evidence

The newly developed systematic reviews and existing systematic reviews of high quality (Score of R-AMSTAR ≥70) were used as the evidence for key clinical questions. After the completion of the newly developed systematic reviews, the guideline development group assessed the strength of the body of evidence using the GRADE approach.

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

Going from Evidence to Recommendation

According to the GRADE approach, the guideline development group adopted the GRADE grid and used a modified Delphi technique to develop the grade of recommendation. In this process, they considered the patient value and preference, economic factors, benefits and harms and quality of evidence together.

Patient Value and Preference

The guideline development group conducted a survey to acquire the information about patient values and preferences.

Economic Factors

The guideline development group considered the economic factors from the cost of non-pharmaceutical therapies and cost of Chinese patent medicine.

Consensus Rules

Here are some rules about the consensus:

> Except "0", the vote of any choices is more than 50%, which is deemed to reach a consensus. The guideline development group can make a decision about the direction and strength of the recommendation.
> The vote of any two choices (happened simultaneously at the right of "0" or the left of "0") is more than 70%, which is deemed to reach a consensus. The guideline development group can make a

decision about the direction of the recommendation, and the strength of the recommendation is "weak".

And, the other situations are not deemed to reach a consensus.

Result - Going from Evidence to Recommendation

Patient Values and Preferences

A total of 217 subjects took part in their investigation of patient values and preferences. There were 72 men and 145 women, aged from 18 to 72 years. The results are as follows:

When patients chose the treatment for primary headache disorders, first, they would consider the cure, reducing recurrence, low incidence of adverse reactions, and then, the convenience of treatment and rapid pain relief and, last, the treatment cost and health insurance.

When patients chose the treatment for primary headache disorders, they would choose non-pharmaceutical therapy, and then the pharmaceutical therapy.

When patients chose non-pharmaceutical therapy, they would choose acupuncture and tuina, and then other non-pharmaceutical therapies.

When patients chose pharmaceutical therapy, they would choose Chinese patent medicine, and then Western medicine.

Recommendation Consensus

A total of 21 experts (see Table 1 in the Appendix [see the "Availability of Companion Documents" field]) took part in the consensus conference. On the basis of quality of evidence, benefits and harms, patient value and preference and economic factors, the guideline development group conducted a 3 rounds consensus and developed 15 recommendations. Consensus results of each round are presented in Table 2, Table 3 and Table 4 in the Appendix.

Rating Scheme for the Strength of the Recommendations

Strength of Recommendation

Recommendation	Benefits and Risks
Strong "Must do"	Benefits clearly outweigh risks
Weak "Might do"	Benefits might outweigh risks
No clear recommendation	Benefits are equal to risks OR uncertain
Weak "Might do"	Risk might outweigh benefits
Weak "Must not do"	Risks clearly outweigh benefits

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The guideline was reviewed using the Appraisal of Guidelines for Research and Evaluation II (AGREE II)

as the evaluation tool (Scope and purpose: 79%, Stakeholder involvement: 78%, Rigour of development: 78%, Clarity of presentation: 71%, Applicability: 70%, Editorial independence: 81%). The reviewers consist of a multidisciplinary group of individuals (including doctors of Traditional Chinese Medicine, nurses, methodologist, etc.). The guideline was adjusted by consensus of these reviewers and approved by the China Association of Chinese Medicine.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- A priority aim and benefit of implementing the recommendations in this guideline would be to improve the percentage of individuals who are able to meet their treatment goal of improving the headache condition.
- The guideline provides therapies for primary headache disorders on the basis of systematic reviews. It gives more alternative options for doctors/patients to choose the suitable treatment.
- Traditional Chinese Medicine therapy has good safety. Clinical studies have not reported serious adverse reactions. Traditional Chinese Medicine therapy can reduce the drug dependence in the long-term use.
- The guideline would guide and standardize clinical rational use of Traditional Chinese Medicine and reduce excessive differences in the use of Traditional Chinese Medicine for primary headache disorders.

Potential Harms

Traditional Chinese Medicine, especially acupuncture and tuina, need professionals to handle.

Qualifying Statements

Qualifying Statements

Clinical practice guidelines are developed to be of assistance to physicians, who want to use Traditional Chinese Medicine in the treatment of primary headache disorders, by providing guidance and recommendations. The guidelines are not intended to dictate the treatment of a particular patient. Treatment decisions must be made based on the independent judgment of physicians and each patient's individual circumstances.

Implementation of the Guideline

Description of Implementation Strategy

The guideline will be published by the China Association of Chinese Medicine. The Guangdong Provincial Hospital of Chinese Medicine will spread it through training and academic communication. They will promote the diffusion by developing the guideline into Chinese and English.

The Guangdong Provincial Hospital of Chinese Medicine will check the implementation of the guideline and update the guideline according to the feedback.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Guangdong Provincial Hospital of Chinese Medicine. Traditional Chinese medicine treatment guideline for primary headache disorders. Guangdong Sheng (China): Guangdong Provincial Hospital of Chinese Medicine; 2018 Jan 30. 5 p. [44 references]

Adaptation

Not applicable: The guideline is not adapted from another source.

Date Released

2018 Jan 30

Guideline Developer(s)

Guangdong Provincial Hospital of Chinese Medicine - Hospital/Medical Center

Source(s) of Funding

This research was funded by State Administration of Traditional Chinese Medicine (Standardization project, No. SATCM-2015-183).

Guideline Committee

Composition of Group That Authored the Guideline

Guideline Development Group Members: Dr. Hui Li, Guangdong Provincial Hospital of Chinese Medicine; Pro. Yan Huang, Guangdong Provincial Hospital of Chinese Medicine; Dr. Yaolong Chen, Lanzhou University; Pro. Xinfu Lian, Guangdong Provincial Hospital of Chinese Medicine; Pro. Yanmei Li, The first affiliated hospital of Henan University of Traditional Chinese Medicine (TCM); Dr. Xingchen Wang, The second affiliated hospital of Shandong University of TCM; Pro. Qingbo Ju, The affiliated hospital of Liaoning University of TCM; Dr. Cunzhi Liu, Beijing Hospital of TCM; Pro. Guoqing Lin, Fujian Provincial People's Hospital; Pro. Yong Zhao, Nanhai Maternity and Child Healthcare Hospital of Foshan Guangdong; Pro. Yuntian Wu, Shenzhen Hospital of Guangzhou University of TCM; Dr. Ning Tian, Guangdong Provincial Hospital of Integrated Chinese and Western Medicine; Pro. Lina He, Community healthcare center of Guangta Street; Yangyang Wang, MPH, Guangdong Provincial Hospital of Chinese Medicine

Financial Disclosures/Conflicts of Interest

In the interest of full disclosure, the Guangdong Provincial Hospital of Chinese Medicine has adopted the policy of revealing relationships workgroup members have with companies that sell products or services that are relevant to this topic. Workgroup members are required to disclose potential conflicts of interest by completing the Conflict of Interest Form. Further details may be requested by contacting lihuitcm@126.com. It should not be assumed that these financial interests will have an adverse impact on the content, but they are noted in the original guideline document to fully inform readers.

Hui Li received a grant from the state administration of Traditional Chinese Medicine.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the Guangdong Provincial Hospital of Chinese Medicine Web site ☐.

Availability of Companion Documents

The following is available:

> Guangdong Provincial Hospital of Chinese Medicine. Traditional Chinese medicine treatment guideline for primary headache disorders. Appendix. Guangdong Sheng (China): Guangdong Provincial Hospital of Chinese Medicine; 2018 Jan 30. 54 p. Available from the Guangdong Provincial Hospital of Chinese Medicine Web site ☐.

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on April 23, 2018. The information was verified by the guideline developer on May 9, 2018.

This NEATS assessment was completed by ECRI Institute on April 17, 2018. The information was verified by the guideline developer on May 9, 2018.

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